11. DEVICE DESCRIPTION

The Callisto TMS System (see Figure 11.1) is designed to be a non-invasive tool for the stimulation of cortical neurons intended for the treatment of psychiatric disorders. This pre-market 510(k) notification seeks clearance of the Callisto TMS System for the treatment of Major Depressive Disorder (MDD) where stimulation is directed to the left prefrontal cortex, a discrete region of the brain involved in mood regulation.

Patient treatment using the Callisto TMS System is by prescription only. The Callisto TMS System must be operated only by a licensed medical professional and will be used in both inpatient and outpatient settings including physician offices and clinics, free-standing psychiatric hospitals, and general medical/surgical hospitals with psychiatric units.

Figure 11.1. Neuronetics Callisto TMS System with Treatment Chair

11.1. Callisto System Description Overview

The Callisto TMS System is a computerized electromec ent that non-invasively produces and delivers brief duration apidly alternating, or pulsed, magnetic fields to the patient's h he induction of electrical currents at spatially discrete regions of the cerebral cortex. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation or TMS. peak magnetic field strength achieved with each pulse is approximately Tesla.

As illustrated in Figure 11.2, the Callisto TMS System consists of a number of hardware and software components, accessories and consumable supplies.

Figure 11.2. Callisto TMS System Main Components

The individual components are briefly described in the following list:

- **Mobile Console** – An enclosed module that forms Callisto TMS System's wheeled base and integrates various subsystems into a single package. It houses or supports the subsystems identified below:
- **Processor Module** – An electronic subsystem that contains the processor and memory required to manage the user interface and system diagnostics.

- **Power Module** – An electronic subsystem that contains the power supply, energy storage, switching circuits, and the controlling logic to manage the timing of current pulses delivered to the treatment coil.
- **Gantry** – A retractable electromechanical arm that helps suspend the coil in space for positioning on a patient's head. It supports various degrees of motion to navigate the coil in free space to move to a desirable location for determining MT and for delivering treatments.
- **Display Arm** – A separate moveable electromechanical arm that supports the display at one end and attaches to the mast at the other end. It enables the user to position the display for comfort and convenience.
- **Mast** – A mechanical pole that extends from the top of the cart and provides support and movement for the Gantry.
- **Display** – An LCD touch screen that provides the primary user interface for system operation. The Display is attached to the display arm for easy positioning.
- **System Software** – A proprietary application that provides the Callisto TMS System graphical user interface (GUI) and incorporates work flow management to guide the system user through a TMS procedure, and also supervises and controls various subsystems.
- **Coil** – An enclosed electromagnet that is mounted to the coil gantry which supports its weight as it is placed against the patient's head. The coil generates the pulsed magnetic field in response to commands from the processor and power modules.
- **Chair –** An electromechanical upholstered seating device that positions the patient comfortably at a desirable height and angle for TMS treatment.
- **Head Support Unit** – A separate attachment for the chair that provides adjustable head support and includes a guidance apparatus to aid in positioning the coil on the patient's head.
- **Positioning Pad Set** – A set of cushions to help enhance the comfort and positioning of the patient in the desired posture for the duration of the treatment.
- **SuperShield –** A one-time use disposable component that serves four primary purposes: 1) it includes a contact sensing element that detects when the coil is properly positioned against the patient's head, 2) it detects the level of the magnetic field being applied by the coil, 3) it reduces the magnetic field at the patient's scalp (without affecting the deeper therapeutic field in the cortex) to aid in patient comfort during treatment, and 4) it provides a clean hygienic surface for each treatment session.

11.1.1. Definitions and Terminology

Table 11.1 provides definitions and terminology used for the Callisto TMS System and related TMS treatment procedures. Highlighted terms refer to the main Callisto TMS System components.

Table 11.1. Definitions and Terminology for the Callisto TMS System

Term	Meaning
Alignment Guide	A subassembly of the Head Support Unit that the clinician uses to register a patient's anatomical landmarks to help identify the coordinates and replicate the motor threshold and treatment positions on the patient's head.
A/P	Anterior/Posterior (used in locating the patient's MT and Tx positions).
APB	Abductor pollicis brevis, the muscle used in the so-called method of limits using observation of twitch in the right APB muscle (thumb).
Brake	"Release to lock" type mechanism used to freeze motion of the gantry components that hold the coil in position.
Coil	Electromagnet that is electrically connected to the Mobile Console and mounted on the gantry. It is placed against the patient's head for therapy delivery during a treatment session.
Contact Sensing	Sensor and software used to detect proper contact between the coil and the patient's head.
Display	Touch screen and LCD combination that provides the primary user interface for the Callisto TMS System.
EMC	Electromagnetic Compatibility
EMG	Electro-myograph. An electronic measuring device that senses neurological evoked potential with electrodes placed on the skin in the area of interest. EMG could be used to sense a thumb twitch when performing motor threshold determination.
Field Replaceable Unit	A system component that is designed to be replaceable in the field. Lower level components are not replaced in the field.
Field Sensing	Capability of detecting the strength of a magnetic field pulse produced by the coil during a test pulse sequence.
Gantry	A retractable mechanical arm that suspends the coil in space for positioning on a patient's head. It enables various degrees of motion to navigate the coil in free space allowing the operator to easily move the coil to a target location for determining MT and for delivering treatment.
Halo	Adjustable mechanical device to which the coil is attached. Includes a manual brake so the freedom of movement can be adjusted by the operator.
Head Cushion	Soft, pliable cushion on the Head Support Unit that provides comfort for the patient's head.
Head Cushion Liner	A disposable, single-use, hygienic paper sheet that is applied to the Head Cushion.
Head Support Unit	Frame and cushion attached to the treatment chair to support the patient's head during a treatment session. The Alignment Guide is also part of this assembly and is used to assist in coil positioning.

Term	Meaning
HIPAA	Health Insurance Portability and Accountability Act, a Federal law that covers healthcare-related data processing identifiers and transactions, and that mandates security and privacy in data processing and communication.
Interval	The period of time between pulse trains (seconds).
Lumbar Cushion	Part of the treatment chair that consists of an adjustable cushion that supports the lumbar region of the patient's back during treatment.
LSOA	Left Superior Oblique Angle. The angle formed by tilting a mid-sagittal plane around an A/P axis (used in locating the patient's MT and Tx positions).
Mast	The vertical pole portion of the gantry.
MDD	Major Depressive Disorder
MEP	Motor Evoked Potential
Mobile Console	System component that comprises the processor module, power module, mast, gantry, display, and display arm.
MT	Motor Threshold level is the setting of the stimulator output needed to stimulate a patient's motor strip at the proper location to cause the thumb to twitch 50% of the time.
MT Assist®	A patented computer program that enables the Callisto TMS System user to determine the MT Level.
MTL	Motor Threshold Level (see MT)
NINDS	National Institute for Neurological Disorders and Stroke
PC	Personal Computer
PDMS	Patient Data Management System, the optional patient data management and reporting software that runs on a separate personal computer and communicates with the Callisto TMS System Mobile Console through a wireless connection.
Positioning Pad Set	Set of cushions to help enhance the comfort and positioning of the patient in the desired posture for the duration of the treatment.
Power Module	Electronic assembly that contains the power supply, power storage, pulse switching circuits, and associated controlling logic.
Processor Module	Electronic assembly that contains the primary computer board and other electronics that control the lower level components of the Callisto TMS System.
Pulse Repetition Rate	Measurement that defines the number of magnetic pulses occurring in a second. The unit for this parameter is in Pulses Per Second (PPS)
Pulse Test	A sy installed. In the test, three pulse re generated to determine if the p agnetic field pulses are not detected nor have an improper level, a failure message is displayed and the user is prevented from performing MT or treatment.
Pulse Train	The group of electromagnetic pulses occurring during the "stimulation time".
Save MT	A feature in the MT Assist ® software that permits the clinician to save a patient's MT level setting for future recall and reference.
Side Pad	Soft, pliable cushion that provides lateral support to the patient's head.
Simple View	An MT Assist® application screen that lists the patient's MT level, the MT search pass number, and a progress bar for the current search. (See also, Tabular view.)

Term	Meaning
SMT Unit	"Standard Motor Threshold". The units used for stimulator output setting. 1.0 SMT corresponds to a average MT level or an induced electric field at a 2cm depth of 130V/m.
Stimulation Time ("Stim Time")	The length of a pulse train (seconds).
SuperShield	A single-use disposable integrated flexible circuit that must be attached to the coil prior to treatment. Its functions include contact sensing, magnetic field detection, and reduction of the field induced in the patient's scalp.
System Processor Board	A printed circuit board containing the main processor.
System Software	The main system software. It resides on the System Processor Board in the Processor Module and incorporates all high level system functions such as graphical user interface, machine state management, supervision and monitoring, communication with subsystems and logging of errors.
Tabular View	MT Assist® application screen that lists for each pass in table format the MT level, the MT Assist® pass number, and a yes/no field for the clinician to record the observation of the patient's thumb twitch. (See also, Simple view.)
Treatment Coil	The active electro-magnetic coil that is connected to the mobile console and placed against the patient's head for treatment delivery during a treatment session. The coil incorporates logic for processing signals from the SuperShield and control buttons, and communicates with the system processor.
TMS or rTMS	Transcranial Magnetic Stimulation (TMS) is a method of using very short pulses of magnetic energy to stimulate nerve cells in the brain. "TMS" will be used synonymously in this submission with Repetitive Transcranial Magnetic Stimulation (rTMS) which refers to TMS with repetition rates greater than 1 pps.
Treatment Chair	Patient treatment platform in the form of a chair that seats the patient comfortably at a electro-mechanically adjustable heights and angles (between 45° and 90°) for treatment. The Head Support Unit attaches to the chair.
Treatment Record	Electronic record containing the details of the patient's treatment sessions.
USB	Universal Serial Bus. Port used to connect external devices to the Callisto TMS System for service and loading software.

11.1.3. Product Structure

The Callisto TMS System will be offered in the configurations indicated in Table 11.2

Table 11.2 List of Callisto TMS System Configurations and Associated Components

Component	Single Console Configuration	Multiple Console Configuration
Mobile Console • Gantry and Coil Suspension • Electronics Enclosure • Power Module • Processor Module • Display • Cables • Covers	Standard	Standard
System Software 1.0	Standard	Standard
Patient Positioning Package • Head Support Unit (includes Coil Positioner) • Head Cushion	Standard	Standard
Treatment Chair (alternative chairs must meet Neuronetics compatibility specifications)	Optional	Optional
Treatment Coil • Low Loss Ferromagnetic Core • User controls (locks, power) • Signal Processor • SuperShield Interface • Cable	Standard	Standard
Consumables Starter Kit • SuperShields 50 pack • Head Cushion Liner Box of 100 • Side Pad 3 ea • Side Pad Boot 50 pack	Standard	Standard
Callisto TMS System User Manual	Standard	Standard
Patient Data Management Software 1.0 (requires an external PC and software with wireless connections to mobile consoles)	Optional	Required with 2-4 Mobile Consoles

Component	Single Console Configuration	Multiple Console Configuration
Patient Data Management Package • PDM Software 1.0 • Off-the shelf pre-loaded computer with keyboard, display (Service provided by computer manufacturer) • Wireless Transceiver • Printer • Set-Up	Optional	Optional
Cushion Set • Seat Cushion • Lumbar Cushion	Optional	Optional

Additional supplies and consumables are available in quantities as needed and can be ordered as indicated in Table 11.3

Table 11.3. Other Supplies and Consumables

Item	Packaging
SuperShield	5 Pack 15 pack 50 pack
Head Cushion Liner	100 pack
Side Pad Boot	100 pack
Ear Plugs	1 Box of 200 pairs

11.1.4. Field Replaceable Units (FRUs)

If a user encounters a system malfunction, Neuronetics will replace the highest level of unit to which the malfunctioning component integrated. This is referred to as a field replaceable unit (FRU

11.1.5. Callisto TMS System Specifications

Table 11.5 shows the system specifications for the Callisto TMS System (single mobile console configuration).

Table 11.5. System Specifications for the Callisto TMS System.

11.1.6. Patient Data Management System (PDMS)

The PDMS software is designed to operate on a stand-alone personal computer that may be linked to one or more mobile consoles through a wireless TCP/IP communication link. This computer is offered as a fully configured option from Neuronetics or may be purchased separately by the user. Table 11.6 shows the computer requirements for the optional Patient Data Management System (PDMS). The PDMS functionality is described more fully in Section 11.2.3.

Table 11.6. Computer Requirements for the Patient Data Management System (PDMS)

11.1.7. Future Upgrades and Related 510(k) Plans

The Callisto TMS System is designed with a modular and upgradeable architecture to facilitate servic

Table 11.7. Upgradeable Components that are likely to have associated future 510(k) applications

11.2. System Component Descriptions

11.2.1. Mobile Console

The Mobile Console is the central workstation for a TMS procedure using the Callisto TMS System and is the main control center for all Callisto TMS System subsystems. The Mobile Console houses the Power Module, the Processor Module, the Gantry Assembly, Mast, and the Display Arm Assembly. The Mobile Console has an enclosed frame with rear doors for service. This unit provides interfaces for input power, coil power, and networking. Containment in this enclosure keeps these connections out of the reach of the user and out of the patient's view.

As illustrated in Figure 11.4, the Mobile Console is mounted on medical grade locking wheels with sufficient radius to clear elevator thresholds and other small irregularities in floor surfaces. It also has a handle that the user grips when positioning for treatment or moving it to a new location.

Figure 11.4. Callisto TMS System Mobile Console (Side View)

The mobile console accepts power from a standard 15A, 120VAC/60Hz receptacle. For customers who use 240VAC/50Hz power, a compatible power cord will be provided and the system will be configured for 240VAC at the final manufacturing facility.

The Processor Module houses the principal system processor that interfaces with other intelligent subsystems and communicates with the user through its interface with the touch screen. The Processor Module processes operator requests, displays system status, and generates command signals to the internal Power Module which generates current pulses that are applied to the treatment coil. The Processor Module also interfaces through a TCP/IP protocol Ethernet link with the optional Patient Data Management System (PDMS).

The Mobile Console contains the system components listed in Table 11.8.

Table 11.8. Major Mobile Console System Components

Key Components	Brief Description
Power Module (See 11.2.1.1)	The Power Module is a self contained [redacted]
Processor Module (See 11.2.1.2)	The Processor Module is a self-contained electronic [redacted]

Key Components	Brief Description
Gantry (See 11.2.1.3)	The Gantry supports the weight of the coil and allows free movement for easy placement on the patient's head. The Gantry consists of a lateral translation table within the Mobile Console, a vertical mast, a balance arm, and a halo assembly that connects to the coil.
Display (See 11.2.1.4)	The Display consists of an integrated, color, touch screen, flat panel display that is mounted on an adjustable support arm attached to the Mast. It is the primary user interface component.

The Callisto TMS System electronics provide the nd control features that deliver treatment to patients. at are housed in the mobile console: the power module and the processor module.

11.2.1.1. Power Module

The PMP detects the presence of the treatment coil and provides a trigger pulse to the trigger circuit and to th ync Out connector. The pulse rate is adjustable from ulses per second. The stimulation time is adjustable fro conds with

The power module also incorporates a circuit breaker that removes AC power from the unit when tripped.

11.2.1.2. Processor Module

The processor module consists of a single-boar computer comprising a central processing unit (CPU), working (volatile) memory, support circuits, non-volatile memory (flash, hard drive), of working memory. An external hard drive provides non-v memory and stores the software necessary to start up and run the normal treatment tasks, including interfacing to remote units, and supporting maintenance and diagnostics as required. It can also accept and apply software upgrades in the field.

The processor module drives the input/output interfaces as shown in Table 11.9

Table 11.9. Processor Module Input/Output Interfaces

Interface Type	Processor Module Internal and External Communication Interfaces
RS232	
USB	
Network	
LPT1	

Interface Type	Processor Module Internal and External Communication Interfaces
GPIO	
LVDS	
Keyboard and Mouse	
VGA video	
IDE	
Processor on/off switch	
Audio	

11.2.1.3. Gantry

The Gantry consists of a lateral translation table within the Mobile Console, a vertical mast, a balance arm, and a halo assembly that connects to the coil as shown in Figure 11.5.

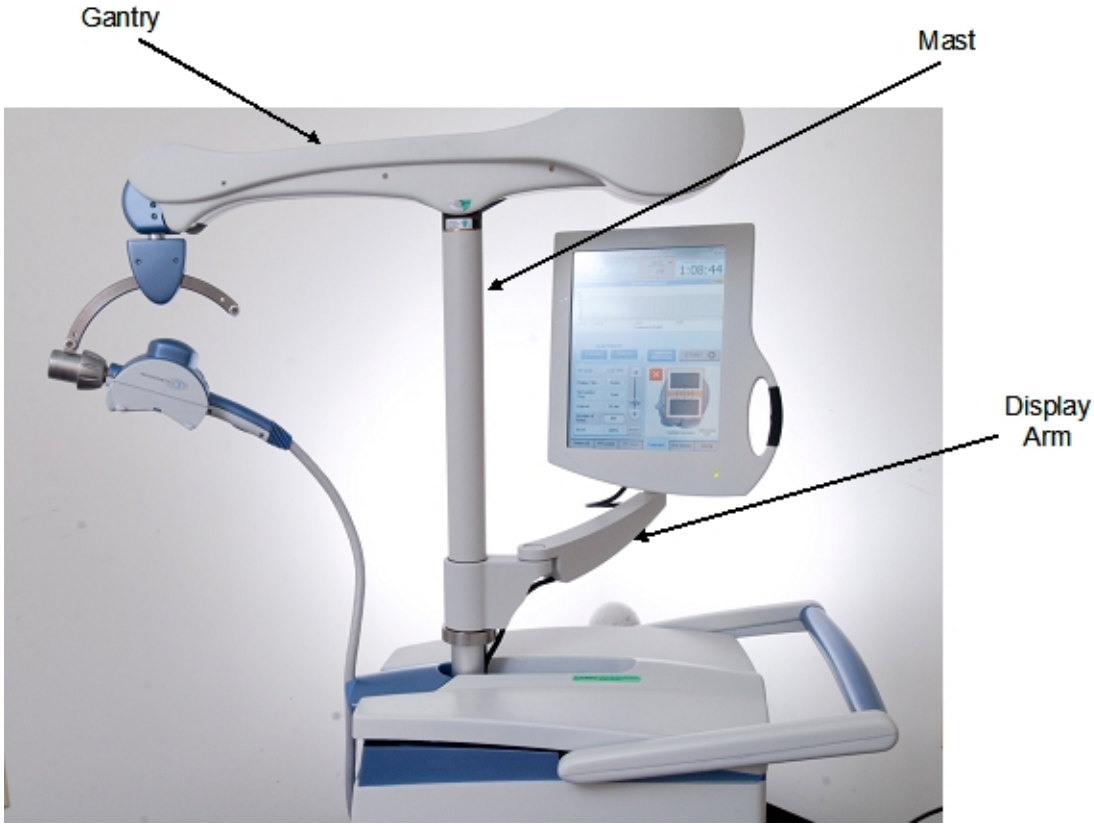

Figure 11.5. Gantry: Showing the Coil, Halo, Mast, Display Arm

The Gantry supports the weight of the coil and allows free movement for easy placement on the patient's head. The gantry incorporates electro-mechanical brakes that automatically lock four degrees of motion when the push button switch on the coil is released, or when commanded under software control. The brakes are designed to lock upon loss of power or when the Mobile Console is not turned on. There are three degrees of freedom in the mechanism that immediately connects to the coil (the "wrist") of the support arm. There is a manual brake to stop motion of the halo ring and a manual brake to adjust rotation resistance of the coil along the handle axis. The coil can be mechanically disconnected using a release pin to facilitate exchanging the coil for service or for research applications (e.g., swapping active and sham coils).

The display arm moves separately from the gantry along a horizontal plane, enabling the user to adjust the position of the display.

11.2.1.4. Display

As illustrated in Figure 11.6, the display has touch-activated images of alphanumeric keys and buttons for user interaction with the system, and displays graphic representations of system activity, messages, and alarms.

Figure 11.6. Display with Touch Screen

The display is capable of presenting graphics, text displays touch controls and provides graphics system resolution of [redacted] It also supports all industry-stan[redacted]eet away in ambient light up to [redacted]oot candles.

The display includes a speaker in the display housing for user/patient alarms. It mounts on the display arm, which is attached to the mast on the Mobile Console.

The position of the display is adjustable for comfortable viewing by the user during various stages of the workflow. It swings both sides to accommodate both left and right side patient treatments (right side use is for research use only). The display's mounting is rigid enough such that during normal touch screen operation, the display does not move.

The display has a viewing angle of at least [redacted] from side to side. It has two degrees of freedom:

- Rotation around the vertical ax [redacted])
- Rotation about the horizontal axis [redacted]

The display presents graphical user interface screens as listed in Table 11.10 which includes a brief description of their functions. More detailed descriptions and views of each of these screens in the order of their use during a MT or TMS treatment session follow the table.

Table 11.10. Graphical User Interface Screens that are presented on the Display

No.	Name	Function
1	Start-Up	Appears upon power up, choose "continue" button
2	Log In	Log in password or Power Down
3	SuperShield Detection	Shows detection of SuperShield and displays Alarms Option button
4	Alarms Option	Lists alarms options and allows disabling
5	Pulse Test Progress	Indicates pulse test in progress
6	Pulse Test Completion	Indicates test pulse complete, allows another test, allows Logout
7	Patient Location	Allows user to select a patient record from the displayed list, scroll up or down the list of patients, search for a patient record, or activate the new patient option

No.	Name	Function
8	New Patient	Allows entry of new patient data, or search for existing patient data
9	Initial MT Measurement	Active MT automatic or manual measurement mode and start button once contact sensing is active
10	MT Location – automatic	Instructions for automated MT, switch button to manual
11	Manual Treatment Initiation	If switch to manual, allows user to control timing and MT level of the pulses administered during the MT search phase, option to switch to automatic MT.
12	Initial MT Level Search – Tabular	Records MT values, switch button to automatic
13	Initial MT Level Search – Simplified	Allows simplified view of MT search data, switch to manual, restart the MT search, save the MT level, pause the process
14	MT Level Search Pause	Allows view of progress of interrupted MT level search, option to resume, to switch to manual, restart the MT search, save the MT level
15	MT Level Search Completion	Provides results of automated MT process, switch to simple view, switch to manual MT, restart MT assist, save MT values, start a treatment session.
16	Treatment Preparation Pop-Up	Enables the user to display the system start screen.
17	Treatment Start	Enables the user to select the standard protocol or to choose to enter a custom protocol. Enables the user to start a treatment session.
18	Custom Protocol	Enables the user to specify a customized protocol.
19	Normal Treatment	Enables the user to monitor the progress of a treatment session.
20	Treatment Paused	Displays treatment progress up to the time treatment was paused.
21	Treatment Termination Confirmation Pop-up	Provides a confirmation opportunity for termination of a treatment session.
22	End Session	Displays a summary of a treatment session.
23	Wireless Operation	Enables the user to establish a wireless connection between the Callisto TMS System unit and the computer that runs the PDMS.
24	Shutdown	Provides a confirmation opportunity for shutting down the Callisto TMS System processor module.
25	Administration Diagnostics	Displays a list of events. Provides access to administrative functions: database back-up and recovery, wireless communication, touch screen calibration, version confirmation, and protocol editing.

No.	Name	Function
26	System Configuration	Enables the access to the following system information for changes: user information, date and time, and custom protocols. Displays a list of alarms.
27	User Update Screen	Enables the system administrator to change a user's information or to delete a user from the system's list of authorized users.
28	Software Update Screen	Enables an authorized user to download and install a software update.
29	Edit Mobile Console Name Screen	Enables the system administrator to change the mobile console name or location.
30	Edit Custom Protocols Screen	Enables the system administrator to add, change, or delete a protocol.
31	Touch-screen Calibration Screen	Enables the system administrator to run an automated calibration routine to ensure touch screen accuracy.

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11.2.1.5. Mobile Console Connections and Main Control Switches

Four data ports are provided at the rear of the Mobile Console as well as the coil standby/on switch and the system reset button as illustrated in Figure 11.38 and described in Table 11.11.

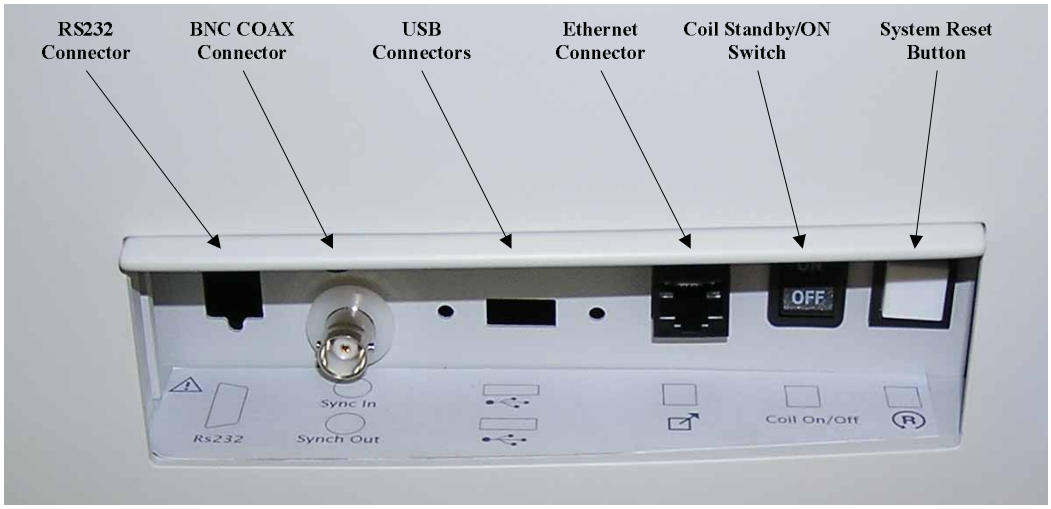

Figure 11.38. Mobile Console Rear Panel Ports and Switches

Table 11.11. Mobile Console Rear Panel Ports and Switches Description

Port / Switch	Description
RS232 Connector	A serial link connection for service and manufacturing use only.
BNC Coax Connector (Sync In)	External trigger input for future research applications.
BNC Coax Connector (Sync Out)	External TTL sync output for externally synchronized research devices.
Universal Service Bus (USB) interfaces (2)	Connection for uploading updated software or downloading report data.
Ethernet Port	An optional hard-wired connection to the Patient Data Management System. The standard network connection to the PDMS computer is wireless.
Coil Standby/On Switch	The coil has its own power cutoff switch on the back of the mobile console as a redundant means of disabling high voltage to the coil. Disconnecting the main coil connector also prevents high voltage pulses from being applied to the coil.
System Reset Button	The mobile console has a button for physically restarting the system in the event that the system fails to respond to operator commands (i.e. software "hang").
Master Power On/Off Switch	As shown in Figure 11.39, the master switch (breaker), which is located on the back of the mobile console, provides a main power switch for the all components of the Callisto TMS System. It is located next to the power cable connector.

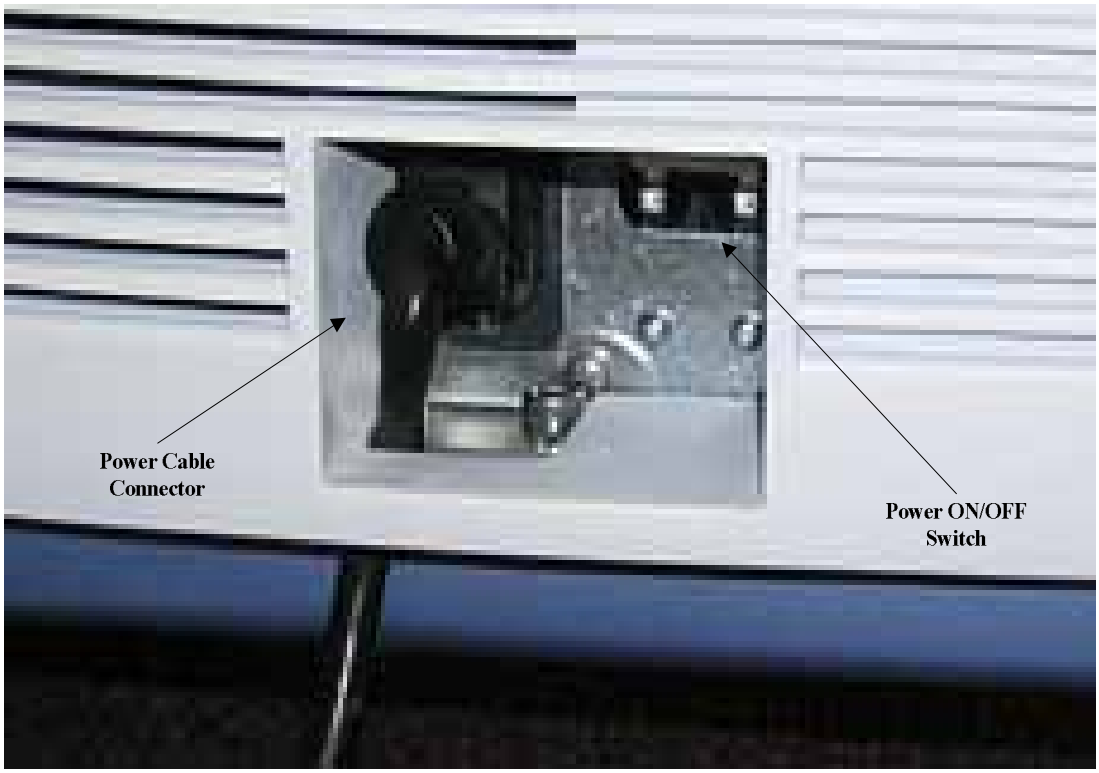

Figure 11.39. Power On/Off Switch and Power Cable Connector

11.2.2. Treatment Coil

Magnetic Field

The coil is an encased electromagnet with associated electronics and controls for MT search and level determination and TMS treatment using the Callisto TMS Syste The patient contact portion of the coil consists of two flat planes at a degree angle that connect with a SuperShield in clinical use. It generates a time-dependent magnetic flux that is proportional to the level set in the system software. The magnetic field intensity is greatest near the point where the pole faces meet. This field intensity drops away quickly from coil. Details of the magnetic field characteristics are provided in this application in Section 11.4.

Coil Control Buttons

Momentary push-buttons are provided on the coil assembly for 1) releasing the gantry brakes that allow proper positioning of the coil on the patient's head, 2) single TMS pulsing for manual MT level determination, and 3) increasing or decreasing the pulse levels during manual MT. Figure 11.40 shows the buttons on the back of the coil. The functions of these buttons are shown in Table 11.12.

Table 11.12. Functions of the Coil Control Buttons

Button	Function
Pulse	In the manual mode of the motor threshold determination process, this button enables the user to trigger a single pulse while holding the coil in place, instead of releasing the coil and using the touch screen to trigger the pulse.
Brake Release	Pushing this button releases the brakes on the gantry and the mast to facilitate relocating the coil. Releasing this button sets the brakes.
Increment/Decrement	These buttons increase or decrease the pulse level either during motor threshold determination process or during treatment.

Figure 11.40. Coil Control Buttons

The coil has an additional brake release button on the underside of the handle, as illustrated in Figure 11.41.

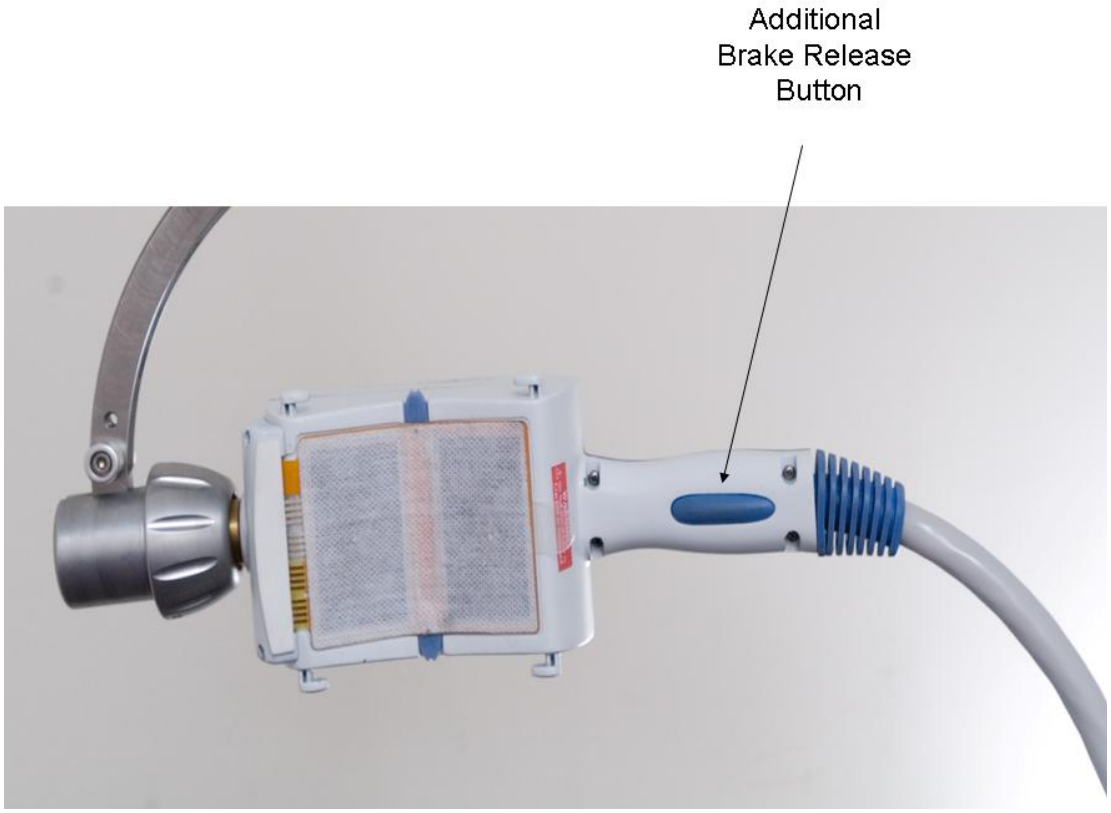

Figure 11.41. Additional Coil Brake Release Button

The coil core consists of a ferromagnetic material that enhances magnetic performance. The coil assembly consists of the core, insulated copper winding, the cable assembly, [redacted] The coil assembly is enclosed in a non-condu [redacted] d is permanently attached to a cable that bifurcates and terminates with two connectors that attach to the Mobile Console. The coil includes an electrical connection for the SuperShield and a mechanical latch to hold the SuperShield in place.

Connection with the Mobile Console

The coil cable connectors have an interlock to prevent the high-voltage circuit from being enabled unless the coil is securely connected to the Mobile Console. This interlock also tells the Processor Module if the connector is in the left or right connector on the power module (for left or right side treatment). This enables the software to communicate the coil configuration position to the operator. The coil electronics store the coil type infor
of coil present.

Figure 11.42. Coil Connector

Coil Interface with SuperShield

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Safety Features

The Callisto TMS System software limits the allowed pulse sequences to avoid unacceptable coil heating (See Section 11.6 for more detail regarding thermal limits)

The brake buttons in the coil handle work with the internal brake controls to give the operator maximum control in positioning the coil. The coil is suspended from the halo, which has a manual position control knob.

Serviceability

The treatment coil is not field-serviceable. The housing is constructed with tamper-resistant screws to prevent unqualified persons from gaining access to the electronics. The entire coil assembly (coil, electronics, and connectors) is a field-replaceable unit.

11.2.3. Head Support Unit

The Head Support System consists of several parts that are designed to provide maximum patient comfort and reliable coil position measurement of the patient's MT locations.

The Callisto TMS System Head Support Unit was shown in validation studies to provide the same level of reproducible measurement, alignment and realignment on the patient's head as for the Model 2100 TMS System that was used in Neuronetics' clinical trials. The comparative validation study and results are described in Section 11.4.1.2.

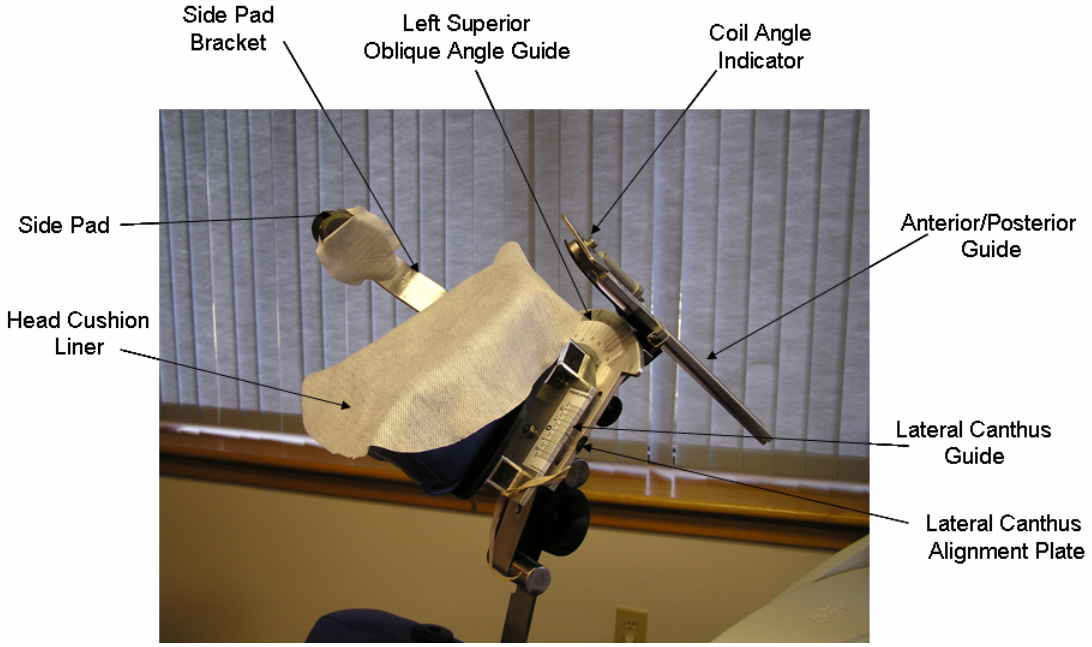

Figure 11.43. Head Support Unit

The head support liner covers the head support cushion, which is a separate cushioned mechanical attachment mounted on the patient chair that provides comfortable support for the patient's head during treatment sessions. It can be set at different heights, angles and distances to accommodate a range of patient positions in response to patient physical characteristics. Specifically, it has degrees of freedom that enable the user to adjust the head support in the anterior-posterior as well as the inferior-superior directions of the patient.

The head support system offers the patient further comfort through the use of a side pad that could be set up both on left or right side of the patient's head. The side pad is mounted on the side pad bracket, which the operator can move toward or away from the side of the patient's head for comfort. During treatment, the side pad is covered by a disposable side pad liner.

The left superior oblique angle (SOA) guide consists of a pivot arm and an angle indicator located behind the head support cushion. The SOA guide adjustment knob holds the SOA guide in position. ning this knob enables the user to set the AP guide at an SOA up to eft or right from the center during the SOA measurement proces oosening this knob also enables the user to move the SOA guide and AP guide to from center for measurement of the lateral canthus position.

The AP guide is a straight flat scale that is held in place by a latch. Releasing this la h enables the user to move the AP scale forward or backward up to 8 inches. When the AP measurement has been established, the er secures the AP guide location by re-engaging the retainer latch.

The lateral canthus guide is a flat scale oriented in the patient's superior/inferior direction and located behind the head support cushion. The lateral canthus alignment plate, which also supports the SOA guide and AP scale, is held in place by the lateral canthus locking knob. Loosening that knob enables the er to raise or lower the lateral canthus alignment plate vertically up to inches from its center location. Tightening the knob holds the al ment plate in place when the lateral canthus measurement has been established. The user must then read and record the intersection of the lateral canthus guide and the pointer on the edge of the lateral canthus alignment plate.

The coil angle indicator is attached to the end of the AP guide. It is a ial scale that enables the user to record the position of the coil up to ° to the left or right of the center location. It is held in place by a sion screw.

In preparation for a Callisto TMS System treatment session, the user applies the recorded MT location measurements to position the coil against the patient's head. The user then installs the coil retainer to hold the coil in place for the duration of the treatment session.

11.2.4. System Software Description

The system software provides the main user interface, guides the user through a clinical workflow (described in Section 11.2.1.4), manages user, patient and configuration data, drives commands to a connected power module to deliver pulses for both treatments and motor threshold determination, monitors status data from connected processors, produces audible tones for both the user and patient, controls the operation of the brakes on the gantry and translation table, and interfaces with an optional Patient Data Management System (PDMS).

The main software components of the Callisto TMS System are listed in Table 11.13 and are described in more detail in this pre-market 510(k) notification in the sections noted.

The system software executes on a PC located inside the Processor Modul

The system software provides:

- Management of the screen display on a touch monitor and receives user input from the touch screen.
- Receipt of push-button, contact sensing, field detection, and SuperShield data from the coil interface processor and writes updates of SuperShield states to the coil interface processor.
- Management of pulse sequence parameters, and provides start, stop and pause commands to the power module processor. The system software receives a temperature high indicator, a coil location indicator, and a high temperature indicator from the power module processor.

Table 11.13. Cross-Reference of Section Numbers to Key Software Components.

Section	Software Component	Function
16.2.1	System Software	All Graphical User Interface Functions
16.2.2	Embedded Power Module Firmware	Power module commands/ pulse delivery/monitoring functions
16.2.3	Embedded Coil Interface Module Firmware	SuperShield interface/coil button interface
16.2.4	Patient Data Management System (PDMS) Software	Remote and off-line patient data management

11.2.5. Patient Data Management System (PDMS) Software Description

The optional Patient Data Management System (PDMS) is an application that runs on a PC connected using wireless or cabled Ethernet to one or more Mobile Consoles running the system software. Further description is found in Section 16.2.4. With the PDMS, the user can do the following:

- Enter patient data through a standard PC keyboard, instead of through the touch screen
- Enter depression scoring types (PGI, CGI, etc.) for each patient
- Modify existing patient data through a keyboard
- Display and print treatment session and patient summary reports
- Configure quick buttons for connected Callisto TMS Systems
- Store treatment and MT data from several systems
- Download software to connected Callisto TMS Systems
- Manage user IDs and passwords
- Back up patient data, MT and treatment data, user IDs, and system preferences to and restore data from media such as CDs
- Export patient, MT, and treatment data to Microsoft Excel™
- Configure automatic log-out intervals.

In addition, Neuronetics technicians use the PDMS for retrieving HIPAA-compliant registry data. Table 11.14 lists the screens displayed in the PDMS application.

Table 11.14. PDMS Screens

No.	Screen
1	Patient List Screen
2	List Users Screen
3	New User Pop-Up Window
4	Change User Information Screen
5	Add Patient Pop-Up Window
6	Delete Patient Confirmation Pop-Up Window
7	Change Protocol Pop-Up Window
8	Treatment Session Report Window
9	Therapy Patient Summary Report Screen
10	Add Patient Score Pop-Up Window
11	Edit Score Type Pop-Up Window

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11.3. Patient Contact Components

A typical treatment session with the Callisto TMS System has a duration of 30 to 45 minutes. During that time, the patient is in contact with the Callisto TMS System parts listed in Table 11.15.

Table 11.15. Patient Contact Components of the Callisto TMS System

Component	Function	Frequency of Use	Materials	Manufacturer
Head Cushion	Cradles the patient's head comfortably in the correct position for treatment	Multiple-use (Normally covered with a Softesse liner; incidental contact only)	Vinylized Fabric Cover Widely used in salon and dental chairs.	Production Head Cushion manufacturer to be selected before manufacturing pilot build
Side Pad Liner	A hygienic barrier covering the side pad that provides lateral support to the patient's head	Single-use (30-40 minutes contact per session)	c used in patient gowns and wound care.	Fabric
Head Cushion Liner	Liner over head cushion as a hygienic barrier	Single-use (30-40 minutes contact per session)	ic used in patient gowns and wound care.	Fabric
Coil Housing	Encloses the coil which delivers magnetic field pulses to the patient	Multiple-use (Normally the SuperShield interposes; incidental contact only)	Plastic commonly used in consumer devices such as telephones and helmets.	Production molding supplier to be selected before manufacturing pilot build
SuperShield	Placed on face of coil; provides contact sensing, field detection, reduced surface magnetic field, and a hygienic barrier	Single-use (30-40 minutes contact per session)	used in patient gowns and wound care.	Fabric manufactured by
Treatment Chair (This is an accessory to the Callisto TMS System. It is an off-the-shelf chair used in salons and spas)	Seats patient in treatment position	Multiple-use (30-40 minutes contact per session)	Vinylized Fabric Cover Widely used in salon and dental chairs.	

The materials used in manufacturing these components were selected for their effectiveness, safety, and comfort. None of these components contain latex. These components are either very common m s used in many settings where there is frequent dermal contact (e.g., and vinylized fabric) or meet the requirements of International Sta ISO10993 (e.g.

All patient or user-contact materials meet the A Guidance G95-1 or ISO 10993 as discussed further in Section 15 of this submission.

Handling and cleaning of multi-use components is described in the User Manual. The manual also indicates that the single-use components are consumable and must be replaced for each treatment.

11.4. Refinements Made To the Neuronetics Clinical Trial TMS System

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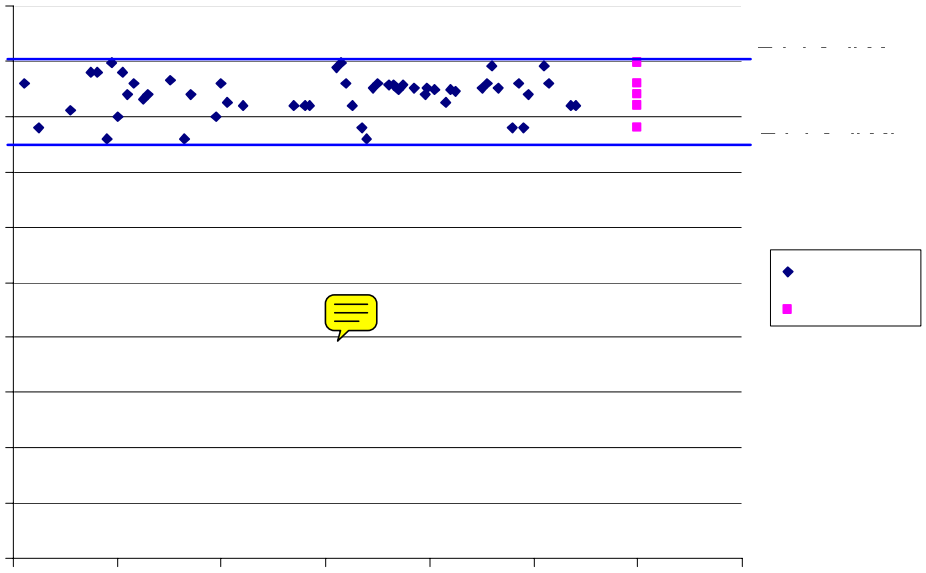

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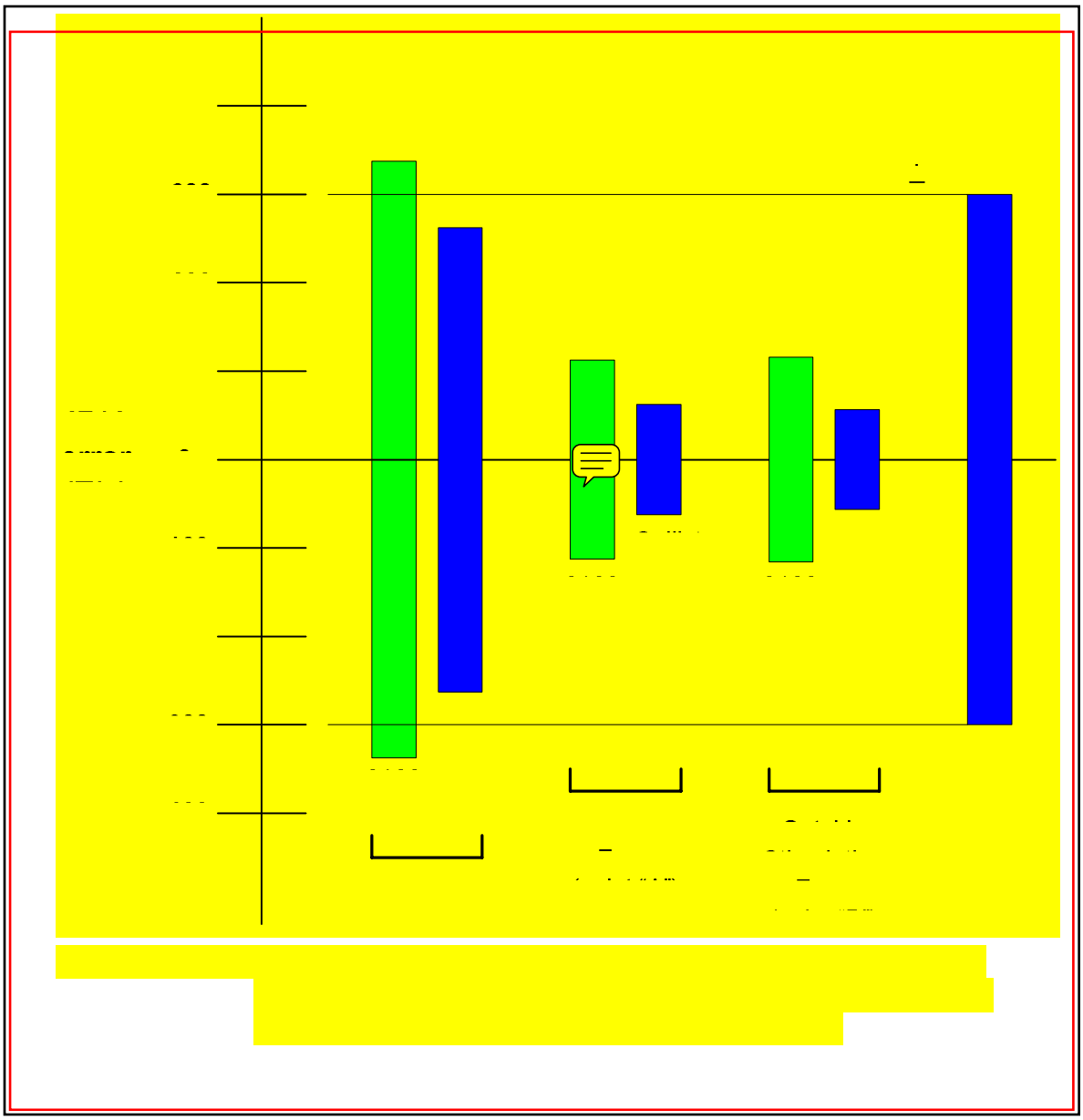

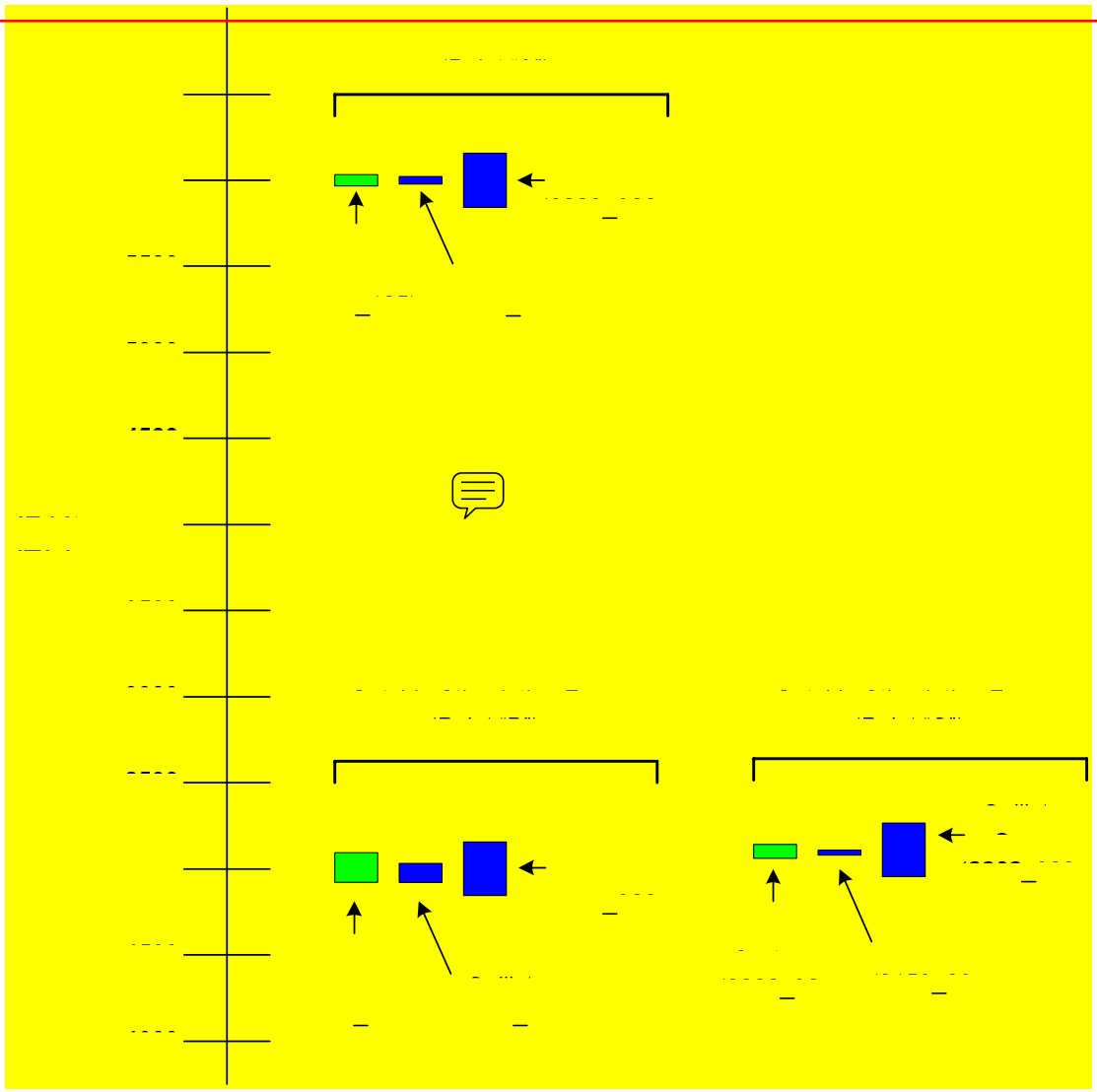

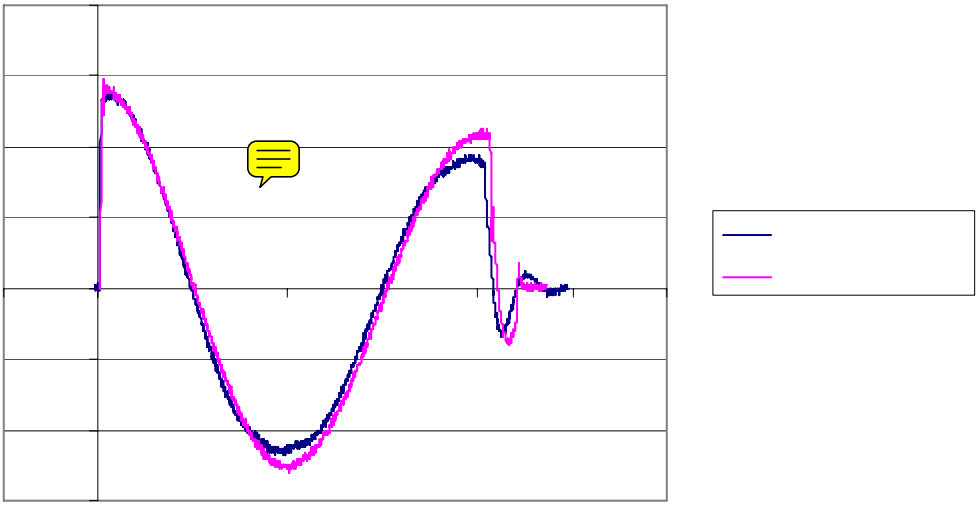

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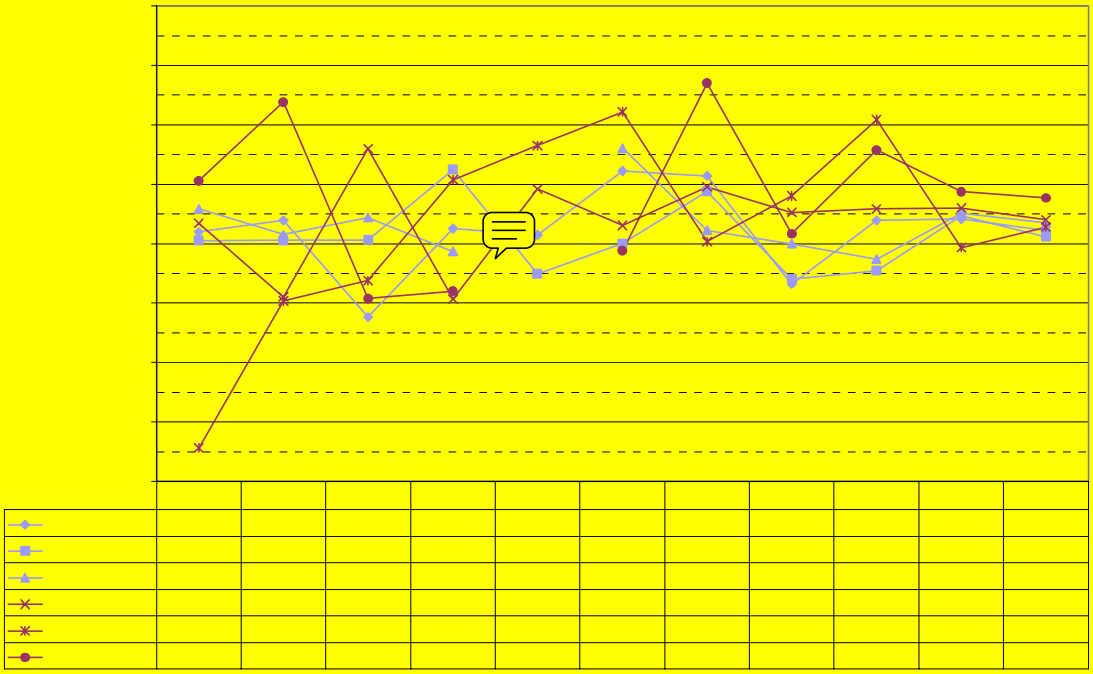

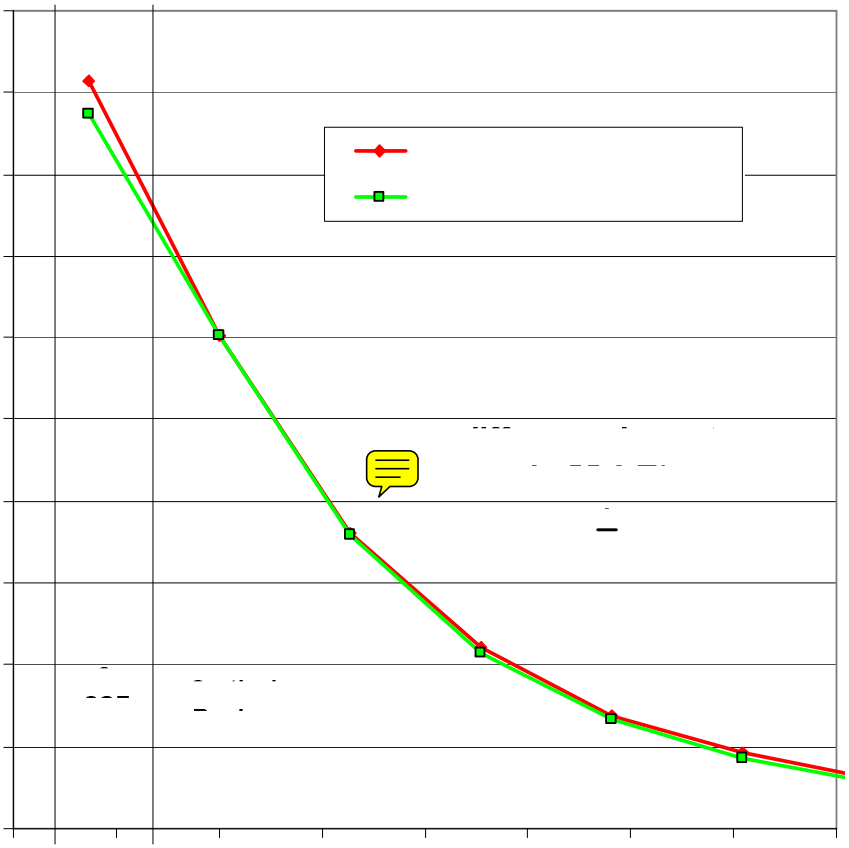

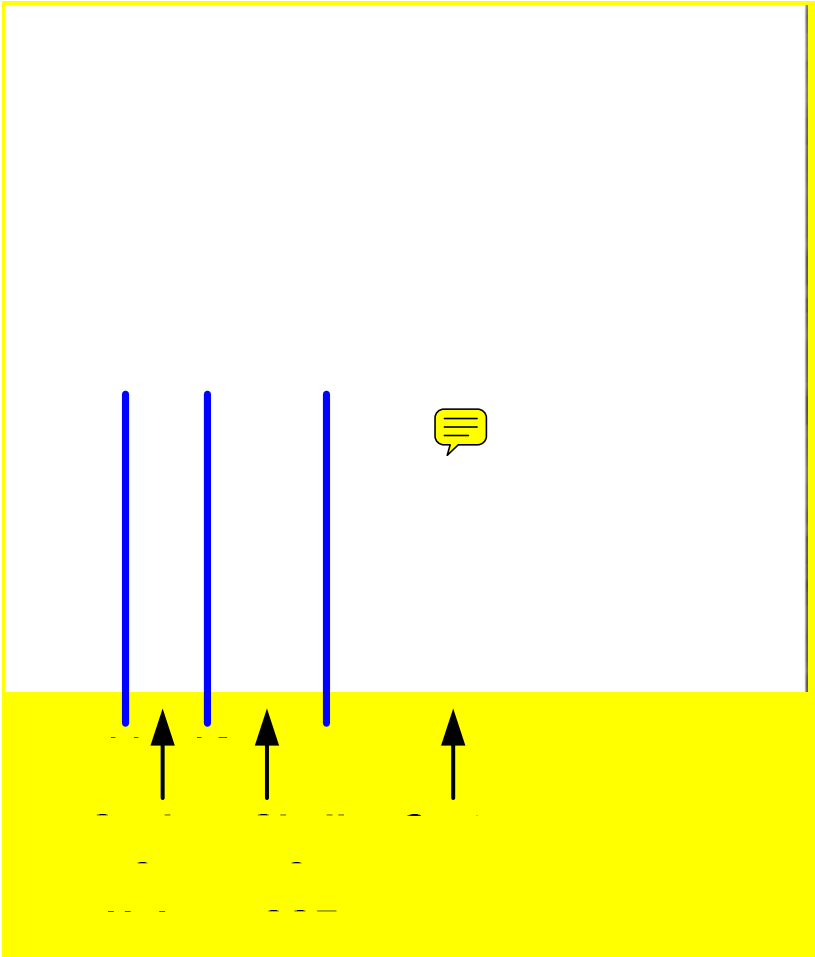

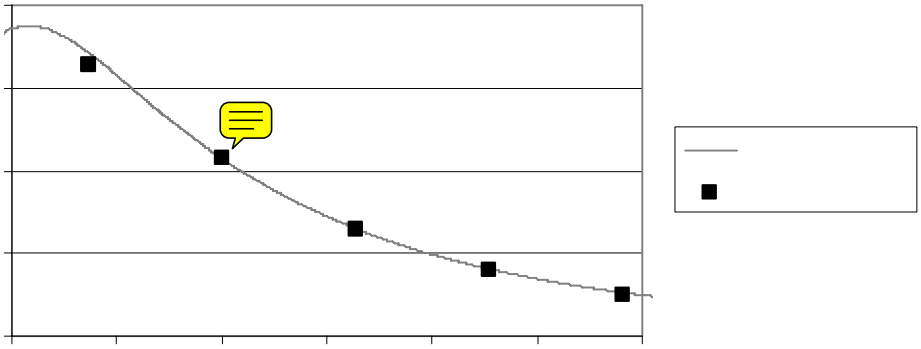

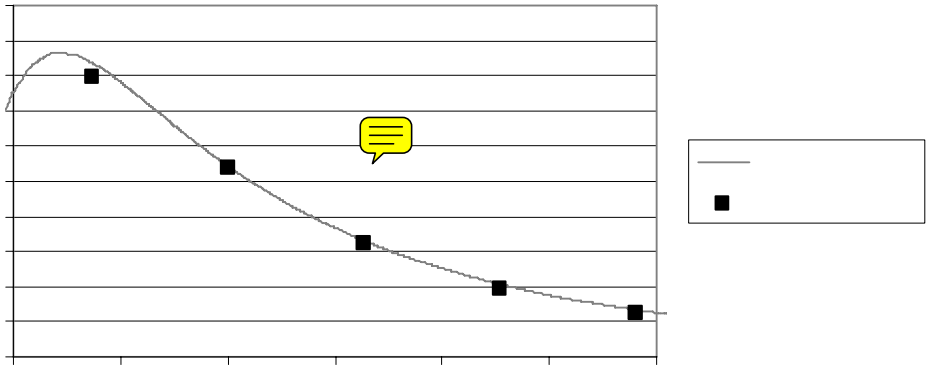

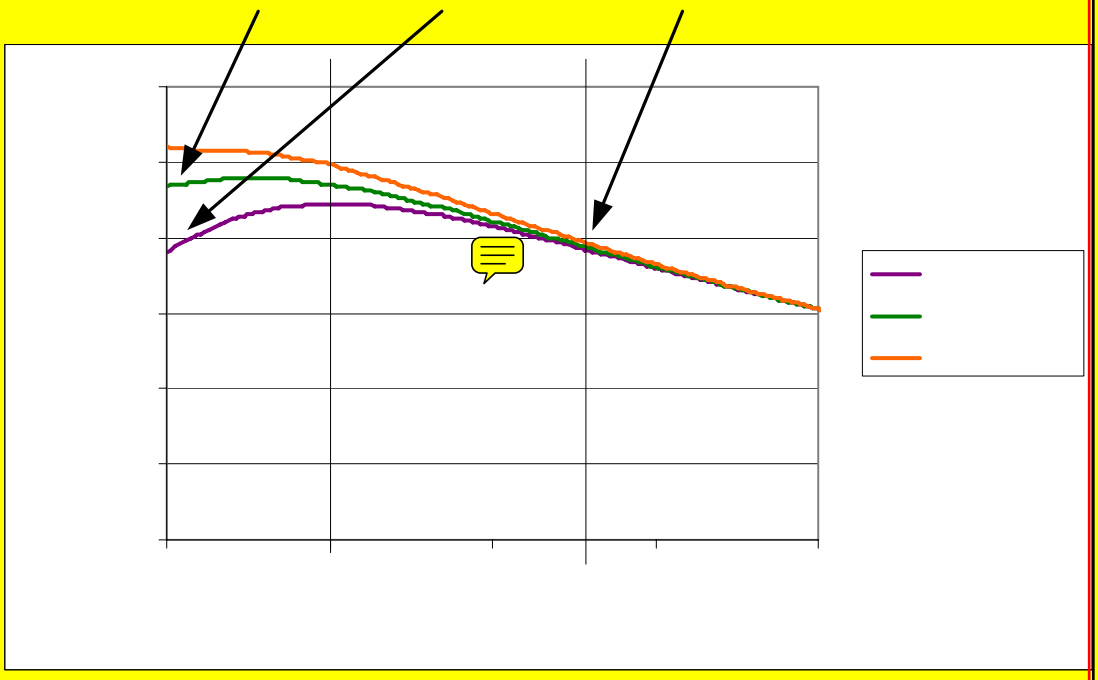

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11.6. Product Safety and Certification Overview

Neuronetics is committed to a rigorous approach to product safety and certification testing, which includes the following:

- Design, manufacture, distribution and sale of the Neuronetics Callisto TMS System in compliance with 21 CFR 820, FDA Quality System Regulations and certification to ISO 13485:2003, Quality Systems – Medical Devices Requirements for Regulatory Purposes as described further in Section 11.7.3 of this pre-market 510(k) notification.
- Certification to EN60601- ctrical Equipment – General Requirements for Safety". will determine compliance with this certification, whi d world-wide as ensuring a high degree of general electro-mechanical safety.
- Certification to the EN60601-1-2 electromagnetic compatibility (EMC) standard. This certification will be completed at
- A Risk Analysis in the form of an FMEA (Failure Modes and Effects Analysis) will be completed. This analysis will demonstrate that any significant potential safety hazards are mitigated.
- An assessment of any potential health effects due to long term exposure to electromagnetic radiation will be completed by an independent expert consultant.

11.6.1. EN60601-1 Compliance

Prior to market release, Neuronetics will work with o obtain certification that the Callisto TMS System complies with EN60601-1 "Medical Electrical Equipment – General Requirements for Safety".

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11.6.2. Electromagnetic Compatibility (EMC) Certification

Prior to market release of the Callisto TMS System, EMC testing to demonstrate compliance with the EN60601-1-2 EMC standard will be completed, as specified in EN60601-1 "Medical Electrical Equipment – General Requirements for Safety".

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11.6.3. Risk Analysis Methodology

The Neuronetics risk assessment process was designed in compliance with ISO 14971, "Medical devices — Application of risk management to medical devices" and is detailed in Neuronetics internal Quality System Procedure 20-71000-000, Risk Management.

Risk assessment is performed during the developme[redacted] form of a Failure Mode Effects Analysis (FMEA). [redacted]

Risk Assessment continues as part of the manufacturing and distribution process using the final design FMEA as a guide. The principle inputs for this ongoing risk assessment are obtained from Neuronetics' quality system processes regarding purchasing, nonconforming material, corrective and preventive actions, and customer complaints. Neuronetics' senior management participate in the review and approval of these inputs and review risk assessment changes as part of Neuronetics' process of quality system management review.

11.6.4. Effects of Magnetic Field Exposure

An analysis of the potential effects of exposure to TMS magnetic fields was conducted by [redacted], an expert who is widely published in the field of bioeffects of electromagnetics radiation, and who has participated in numerous MRI safety and standards committees. The full report is included in Appendix 13. The analysis considered many mechanisms and bioeffects including:

- induced translational forces,
- interaction with implanted devices,
- effects on nerve conduction velocities,
- voltages induced due to flowing blood or moving particles,
- comparison to power line exposure,

- chemical reaction rates,
- proton tunneling in DNA,
- single photon interactions,
- cardiac stimulation,
- T-wave modifications,
- mutagenic effects, and
- temperature rise due to power deposition.

The analysis concludes that there appears to be little or no evidence of harmful effects from magnetic field exposures (experimentally up to 8 T in this review). Theoretical concerns start as low as 10 T. These and other data led the U.S. Food and Drug Administration to consider static fields below 4 T to be a non-significant risk. Also, the time varying nature of the TMS field is of significantly low frequency that translational forces and tissue heating are negligible. In summary, experimental and observational evidence indicate that exposure to the magnetic fields produced by the Neuronetics' TMS coil does not present any significant risk of causing acute or long term adverse effects.

11.7. Manufacturing Process Overview

This section provides an overview of the manufacturing process for the Neuronetics Callisto TMS System and related accessories. It also describes key product development activities that were conducted for the clinical trial Model 2100 TMS System. More detail on the manufacture of the Model 2100 TMS System is provided in

Nearly all activities related to production of the Callisto TMS System are sourced to external suppliers, all of which are qualified through Neuronetics Quality Management System. These suppliers have manufacturing responsibilities that interlock with Neuronetics' processes and are under Neuronetics' control at all levels: quality, design, change control, production

Table 11.31. Responsibilities of Commercial Manufacturing Partners

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Table 11.32. Responsibilities of Clinical Manufacturing Partners

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11.7.1. Manufacturing Process and Controls

New Product Development

Neuronetics follows a QSR-compliant product development process for all new products. This is defined in Neuronetics 20-73000-000, Product Development Process Procedure. During product definition, design, implementation, verification and manufacturing transfer, Neuronetics' contract engineers and manufacturing perso

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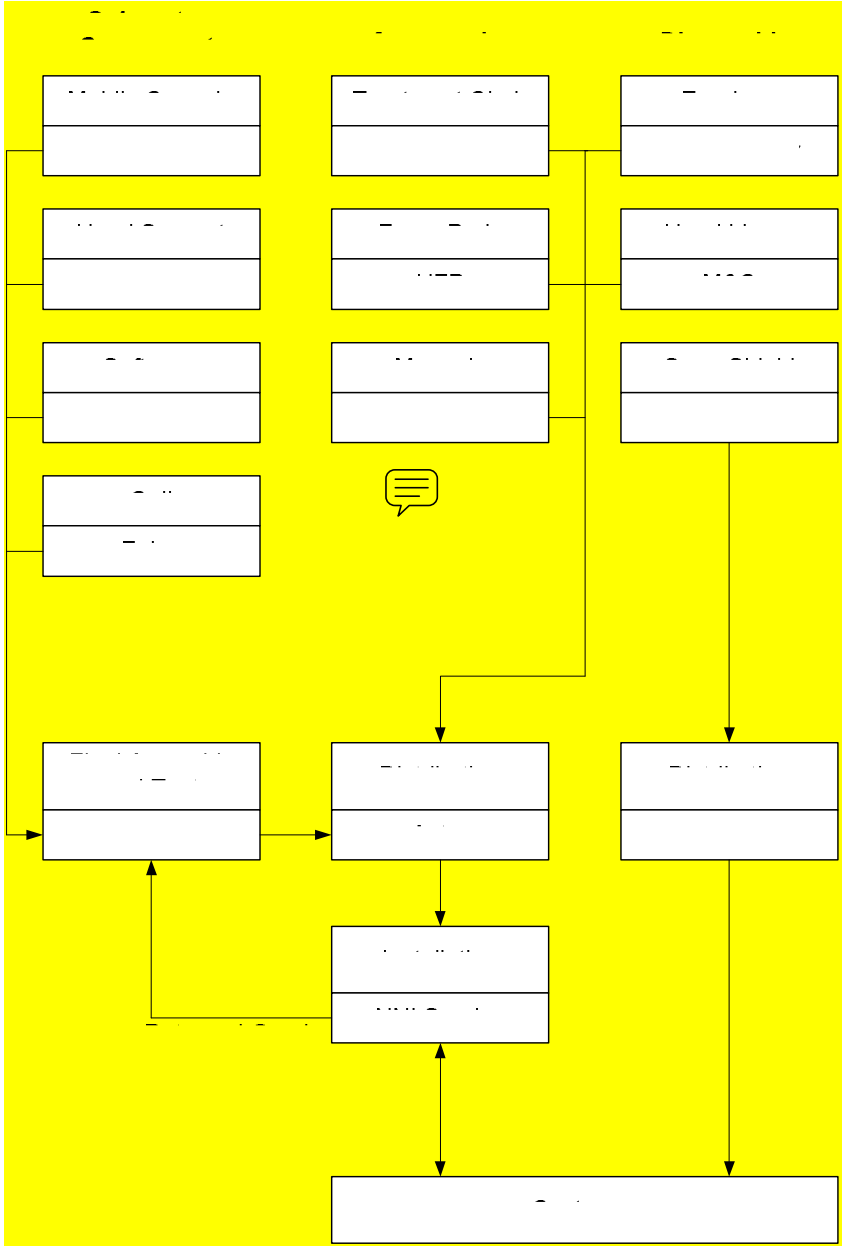

11.7.2. Clinical Trial Model 2100 TMS System Manufacture

The manufacture of the Model 2100 TMS System
Neuronetics' clinical trials is described in detail in

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Manufacturing Process Audit

Neuronetics conducted a process audit to ensure that the manufacturing process for the smartcards and treatment coils adhered to the defined procedures, and that patient treatment cards and coils were randomized to the appropriate allocation and labeling. This also included a review of third-party auditing activities, results and any resulting corrective actions. The manufacturing activities of the contract manufacturer and the auditing techniques employed by the third-party auditor were verified and found to be in compliance with Neuronetics requirements.

11.7.3. Neuronetics Quality Management System

Neuronetics' quality management system was designed and is maintained to comply with FDA's Quality System Regulations (21 CFR Part 820).

Neuronetics is certified for compliance with ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes, (Certificate No. FM83724, issued 15 December 2005, expiry date 14 December 2008) for "the design, manufacture, dist nd euromodulation medical devices" by

The manufacturing of the Callisto TMS System and its components is handled by contract manufacturers or packagers that are qualified under Neuronetics quality management system. Neuronetics contractually and procedurally defines it's qualification of contract manufacturers and packagers and of their products and/or services provided, responsibilities, interfaces with Neuronetics and the requirements for Neuronetics pre-approval for any circumstances that may affect product or process quality.